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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR

09/361,829 07/27/99 HEATH

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ARTUNIT PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

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Office Action Summary	Application No.	Applicant(s)		
	09/361,829		HEATH ET AL.	
	Examiner		Art Unit	
	Jeffrey S. Lundgren		1631	
The MAILING DATE of this communication appears on the cov r sh et with th correspondenc address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE $\underline{3}$ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.				
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>Status</li> </ul>				
1) Responsive to communication(s) filed on				
2a) This action is <b>FINAL</b> . 2b) ⊠ This action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims				
4)⊠ Claim(s) <u>1-22</u> is/are pending in the application.				
4a) Of the above claim(s) <u>20-22</u> is/are withdrawn from consideration.				
5) Claim(s) is/are allowed.				
6)⊠ Claim(s) <u>1-19</u> is/are rejected.				
7) Claim(s) is/are objected to.				
8) Claims are subject to restriction and/or election requirement.				
Application Papers				
9) The specification is objected to by the Examiner.				
10) The drawing(s) filed on is/are objected to by the Examiner.				
11) The proposed drawing correction filed on is: a) approved b) disapproved.				
12) The oath or declaration is objected to by the Examiner.				
Priority under 35 U.S.C. § 119				
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).				
a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:				
1. received.				
2. received in Application No. (Series Code / Serial Number)				
3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).				
* See the attached detailed Office action for a list of the certified copies not received.				
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).				
Attachment(s)				
<ul> <li>15) Notice of References Cited (PTO-892)</li> <li>16) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>17) Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ul>	19) 🔲 No		y (PTO-413) Paper I Patent Application (I	

### **DETAILED ACTION**

#### Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-19, are drawn to a computer readable medium, computer,
     control module, and computer module, classified in class 702, subclass
     19.
  - II. Claims 20-22, are drawn to a method of defining a protocol, classified in class 364, subclass 130.
- 2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Group II can be performed manually.
- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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4. During a telephone conversation with Mr. Polglaze on September 18, 2000 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

## Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 1-7, 9-10, and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. (U.S. Patent No 5,773,221, June 30, 1998) in view of Stephens et al. (U.S. Patent No. 5,856,133, January 5, 1999) in view of Dionne et al. (U.S. Patent No. 5,800, 828, September 1, 1998) in view of Bacus et al. (U.S. Patent No. 4,175,860, November 27, 1979).

Claims 1-7, 9-10, and 14-18, are drawn to a computer system for isolating DNA, wherein the isolation procedure comprises adding reagents, mixing reagents, centrifuging reagents, and removing/separating reagents.

Carlson et al., disclose a method of isolating DNA, wherein added reagents are mixed with a sample, centrifuged at a predetermined g-force for a predetermined time, removing certain reagents, adding more reagents, and further centrifugation steps as necessary to isolate the DNA (see column 14 to column 15, line 45)

Carlson et al., do not teach mixing the reagents with an aspirator, or automating the system with computer control.

Stephens et al., disclose a method for isolating proteins, wherein a series of centrifugation, mixing, separating and aspirating steps are used as a means of isolation (see column 46, line 62 to column 47, line 36).

Dionne et al., disclose a method of isolating islets, wherein an aspiration is used for mixing (see column 42, lines 29-37).

Bacus teaches a method and an automated laboratory apparatus for performing said method, and how automation is advantageous over high-throughput, human-performed, laboratory methods (see column 1, lines 31-59).

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From the combined references teaching methods of biomolecule isolation, one of ordinary skill in the art would have had a reasonable expectation of success in producing the invention as claimed. Stephens et al., demonstrates that aspiration is useful with centrifugation, mixing, separating, for although aspiration is applied differently (i.e., aspirating supernatant), an aspiration means is advantageous because it can be used for both mixing reagents (as taught by Dionne et al) and removing supernatant, and would be useful for the isolation of protein as well as the isolation of DNA as taught by Carlson et al. Furthermore, the benefits of automating laboratory methods with machines for high-volume testing are well-known, as supported by Bacus, as the disclosure teaches that automated laboratory systems are advantageous over human-executed methods because of cost, speed and accuracy (also see M.P.E.P. § 2106, and 2144.04). Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al., in view of Stephens et al., in view of Dionne et al., in view of Bacus et al., as applied to claims 7 above, and further in view of Thrush (U.S. Patent No. 5,692,144, November 25, 1997).

Claim 8 is drawn to the computer system of claim 6, wherein a graphical user interface (GUI) is provided for user control of said computer system in executed the user-defined method.

Thrush teaches that GUIs are advantageous software interfaces for computer systems because human error is minimized and the software provides a "user-friendly environment" (see column 1, lines 29-49).

From the combined references involving automation, one of ordinary skill in the art would have had a reasonable expectation of success in producing the invention as claimed. One would have been motivated to utilize a GUI for conveying user-defined instructions to an automated machine systems (i.e., the automated system of paragraph 7), as Thrash demonstrates that GUIs provide a user-friendly environment and minimize human errors. Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

9. Claims 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al., in view of Stephens et al., in view of Dionne et al., in view of Bacus et al., as applied to claims 9-10 above, and further in view of Johnson et al. (U.S. Patent No. 5,584,039, December 10, 1996)

Claims 11 and 19 are drawn to computer means, wherein a dedicated processor is implemented.

Neither Carlson, Stephens, Dionne, or Bacus, specifically teach the use of a dedicated processor.

Johnson et al., summarize the well-known advantages of using dedicating processors in computer systems wherein a processor is responsible for the control of multiple submodules and tasks (see Summary of the Invention).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a dedicated processor with the computer module of Carlson, Stephens, Dionne, and Bacus, because the Johnson et al. disclose the advantages of relieving the CPU by means of a dedicated processor. Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al., in view of Stephens et al., in view of Dionne et al., in view of Bacus et al., as applied to claims 9-10 above, and further in view of Poulter et al. (U.S. Patent No. 6,072,795, June 6, 2000)

Claim 12 is drawn to the control module of claim 9 the use of computer systems with programs wherein said programs are burned into the processor with hard code.

Neither Carlson, Stephens, Dionne, or Bacus, specifically teach the use of computer systems with programs wherein said programs are burned into the processor with hard code.

Poulter et al., disclose the use of computer systems with programs wherein said programs are burned into the processor with hard code (column 6, lines 8-19).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize computer systems with programs wherein said programs are burned into the processor with hard code with the computer module of Carlson, Stephens, Dionne, and Bacus, because the capability of the said processor to require

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less software support. Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al., in view of Stephens et al., in view of Dionne et al., in view of Bacus et al., as applied to claims 9-10 above, and further in view of McNutt (U.S. Patent No. 5,802,389, September 1, 1998)

Claim 13 is drawn to the control module of claim 9, wherein a programmable logic controller is implemented.

Neither Carlson, Stephens, Dionne, or Bacus, specifically a control module, wherein a programmable logic controller is implemented.

McNutt discloses that it is becoming increasingly important to provide programmable logic controllers (PLCs) which provide modular approaches. That is, the ability to enlarge a system by providing additional features and/or additional input/output analog and/or digital I/O. Modular systems allow for adaptation to simple and complex situations as well as increasing in cost in more manageable incremental steps. Further, due to the increased use of PLCs, it is now a de-facto requirement that such controllers be capable of being interconnected in a network type environment and being programmed and reprogrammed through a variety of means.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a PLC with the computer means of Carlson, Stephens, Dionne, and Bacus, because the well-known flexibility and modular nature that PLCs

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offer for automated systems as disclosed by McNutt. Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

#### Conclusion

12. No claims are allowable.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeffrey S. Lundgren whose telephone number is (703) 306-3221. The Examiner can normally be reached on Monday-Friday from 7:00 AM to 5:00 PM (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Michael Woodward, can be reached at (703) 308-4028.

Any inquiries of a general nature relating to this application should be directed to the Technology Center Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1631 using (703) 308-0294. Please notify the Examiner of incoming facsimiles prior to sending papers to the aforementioned fax number. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Jeffrey S. Lundgren, Ph.D.

JOHN S. BRUSCA, PH.D PRIMARY EYAMINED